U.S.C. §103(a) as being unpatentable over Brownlee et al in view of Lu and Lu in view of Brownlee et al, further in view of Bradley.

These rejections are respectfully traversed for the following reasons.

The Examiner has relied on the Brownlee et al reference as teaching an internal cardiac electrogram sensing system that is applicable for use in a dual chamber pacemaker, and this system has a sensing electrode that is located at a distance from the heart to provide improved cardiac signal sensing capabilities. The Examiner acknowledged that the Brownlee et al reference does not specifically teach use of the sensing electrode for the detection of loss of capture.

The Examiner on the Lu reference as teaching an implantable stimulation device and method for detecting capture in a bi-ventricular stimulation device, wherein capture of a stimulated chamber is verified by detecting depolarization in the opposing chamber.

The Examiner stated it would have been obvious to a person of ordinary skill to combine the teachings of Brownlee et al with the teachings of Lu because Brownlee et al and Lu both teach cardiac stimulation devices that can provide dual chamber stimulation, and the Examiner stated it would have been obvious to modify the system taught by Brownlee to include loss of capture detection, because loss of capture detection measures are well known in the art for providing optimum performance for a cardiac pacemaker as taught by Lu.

Applicant respectfully disagrees with this conclusion of the Examiner for the following reasons.

As noted in Applicant's previous response, although the Brownlee et al reference generally states that the sensing electrode therein is used to obtain

(sense) a signal that avoids interference with the pacing electrode, Applicant submits that because bi-ventricular pacing is not specifically described in the Brownlee et al reference, these general statements do not represent a sufficiently specific or sufficiently disclosed solution to the particular problems associated with assessing loss of capture in the context of bi-ventricular pacing, so as to induce, motivate or guide a person of ordinary skill in the field of bi-ventricular pacing, with the requisite level of detail and particularity required by 35 U.S.C. §103(a), so as to make use of the remotely located sensing electrode disclosed in the Brownlee et al reference as a solution to the problem of detecting loss of capture in bi-ventricular pacing.

As also noted in Applicant's previous response, the Lu reference is but one of many examples that discuss the particular difficulties associated with detecting or assessing loss of capture in the context of bi-ventricular pacing. Several other references discussing this problem were described in the introductory portion of the present specification. All of those reference, including the Lu reference, make use of relatively elaborate and complicated timing or detection circuits in order to overcome or circumvent the aforementioned problems in this field. None of those references, including the Lu reference, provides any suggestion whatsoever that a remotely disposed electrode or sensing electrode of the type disclosed in the Brownlee et al reference would have any benefit in the context of solving that particular problem.

Since there is no teaching or suggestion in the Brownlee et al reference that the remotely located sensing electrode disclosed therein does or could have any benefit for use in bi-ventricular pacing, and more specifically have benefit for the purpose of detecting loss of capture in the context of bi-ventricular pacing, and since the Lu reference describes many approaches to detecting or assessing loss of

capture in bi-ventricular pacing, but none of those approaches involves a remotely located sensing electrode, Applicant respectfully submits these two references merely represent different and unrelated knowledge that exists in the field of cardiac pacing, but there is no teaching, guidance or motivation disclosed or suggested in either of those references to justify the use of a combination of those references as a basis for rejecting the claims of the present application under 35 U.S.C. §103(a). In view of the complete absence of any guiding information in either of those references, Applicant submits that if a person of ordinary skill in the field of cardiac pacing had the insight to modify the Brownlee et al reference to, first, change the pacing mode disclosed therein to bi-ventricular pacing and, second, to then make use of the remotely located sensing electrode for the purpose of detecting or assessing loss of capture in bi-ventricular pacing, this would be an insight supporting patentability, rather than a reason for arguing against patentability.

The Federal Circuit stated in *In re Lee* 227 F.3d 1338, 61 U.S.P.Q. 2d 1430 (Fed. Cir. 2002):

> "The factual inquiry whether to combine references must be thorough and searching. ...It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with."

Similarly, quoting *C.R. Bard, Inc. v. M3 Systems, Inc.,* 157 F.3d 1340, 1352, 48 U.S.P.Q. 2d 1225, 1232 (Fed. Cir. 1998), the Federal Circuit in *Brown & Williamson Tobacco Court v. Philip Morris, Inc.,* 229 F.3d 1120, 1124-1125, 56 U.S.P.Q. 2d 1456, 1459 (Fed. Cir. 2000) stated:

> [A] showing of a suggestion, teaching or motivation to combine the prior art references is an 'essential component of an obviousness holding'.

In *In re Dembiczak,* 175 F.3d 994,999, 50 U.S.P.Q. 2d 1614, 1617 (Fed. Cir. 1999) the Federal Circuit stated:

> Our case law makes clear that the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references.

Consistently, in *In re Rouffet,* 149 F.3d 1350, 1359, 47 U.S.P.Q. 2d 1453, 1459 (Fed. Cir. 1998), the Federal Circuit stated:

> [E]ven when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill in the art, that suggests the claimed combination. In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.

In *Winner International Royalty Corp. v. Wang,* 200 F.3d 1340, 1348-1349, 53 U.S.P.Q. 2d 1580, 1586 (Fed. Cir. 2000), the Federal Circuit stated:

> Although a reference need not expressly teach that the disclosure contained therein should be combined with another, ... the showing of combinability, in whatever form, must nevertheless be clear and particular.

Lastly, in *Crown Operations International, Ltd. v. Solutia, Inc.,* 289 F.3d 1367, 1376, 62 U.S.P.Q. 2d 1917 (Fed. Cir. 2002), the Federal Circuit stated:

> There must be a teaching or suggestion within the prior art, within the nature of the problem to be solved, or within the general knowledge of a person of ordinary skill in the field of the invention, to look to particular sources, to select particular elements, and to combine them as combined by the inventor.

Applicant respectfully submits that the complete absence of any guiding or motivating information in either of the Brownlee et al or Lu references makes the Examiner's proposal to combine those references nothing more than an "obvious to try" rejection, which the Federal Circuit has stated on numerous occasions is not sufficient to satisfy the requirements of 35 U.S.C. §103(a). As stated by the Federal

Circuit in *N. V. Akzo v. E. I. Du Pont De Nemours & Co.,* 810 F.2d 1148, 1 U.S.P.Q. 2d 1704 (Fed. Cir. 1987):

> The admonition that "obvious to try" is not the standard under §103 has been directed mainly at two kinds of error. In some cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful....In others, what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it.

As noted in Applicant's previous response, the Brownlee et al reference is clearly of a vintage wherein the term "dual chamber pacing" was not intended to encompass, and was not understood to encompass, bi-ventricular pacing. Instead, the term "dual chamber pacing" at a time contemporaneous with the Brownlee et al reference was understood by those of skill in the field of cardiac pacing as meaning pacing in one atrium combined with pacing in one ventricle. Since the subsequent advent of bi-ventricular pacing, those of ordinary skill in the field of cardiac pacing have recognized that each technique for bi-ventricular pacing must, and should, be investigated on its own, and it should not be assumed that known techniques relating to dual chamber pacing can or should be automatically transferred to bi-ventricular pacing. Analyzing the Brownlee et al/Lu rejection in this context, therefore, falls into the first category noted by the Federal Circuit, namely to "run through" numerous techniques for dual chamber pacing in the hope that one of those techniques might

work for bi-ventricular pacing. As defined by the Federal Circuit, this is an "obvious to try" allegation and does not properly support a rejection under 35 U.S.C. §103(a).

Alternatively, if it is the position of the Examiner that the Lu reference represents a "promising" modification of the Brownlee et al system, even though neither bi-ventricular pacing nor loss of capture are mentioned anywhere in the Brownlee et al reference, Applicant respectfully submits this falls into the second "obvious to try" category described by the Federal Circuit, and again the high level of evidentiary support that is necessary to substantiate a rejection under 35 U.S.C. §103(a) is lacking.

Applicant acknowledges that it can be sometimes difficult to establish a clear distinction between true "obviousness" and "obvious to try." The Federal Circuit has acknowledged as much as well in *In Re O'farrell,* 853 F.2d 894, 7 U.S.P.Q. 2d 1693 (Fed. Cir. 1988), in stating

> [T]he meaning of this maxim is sometimes lost. Any invention that would in fact have been obvious under §103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless non-obvious?

Applicant respectfully submits that the best and most reliable way to answer that question is to attempt to substantiate an obviousness rejection according to the rigorous evidentiary standards cited above, all of which stress the importance of locating a clear teaching, motivation, inducement or guidance in one of the references so as to justify their combination. Applicant respectfully submits that no such evidence is present in either of the references, nor in the general level of skill in the field of cardiac pacing, and therefore Applicant respectfully submits that the

rejection of claims 1-6 and 10-13 under 35 U.S.C. §103(a) is being unpatentable over Brownlee et al in view of Lu should be withdrawn.

The same lack of any motivation, guidance or inducement in either of the Brownlee et al and Lu references is applicable to the rejection of those claims as being unpatentable over Lu in view of Brownlee et al. With regard to that rejection, however, a further factor from the above-cited case law is relevant, namely the requirement under Graham v. Deere to take into account a long felt but unsolved need in the relevant technology, together with the failure of others. As noted above, the Lu reference, and the references discussed in the present specification, represent a litany of various approaches that have been taken by those of ordinary skill in the field of cardiac pacing to detect or assess loss of capture in the context bi-ventricular pacing. None of those previous approaches involves the use of a remotely located sensing electrode, despite the fact that the Brownlee et a reference substantially pre-dates the Lu reference and the references discussed in the present specification. This is persuasive evidence that simply because the use of such a remotely located sensing electrode was generally known in the field of cardiac pacing, as exemplified by Brownlee et al, it is not a simple or obvious matter to recognize that the use of such an electrode could have any benefit in the field of bi-ventricular pacing, specifically for the purpose of detecting loss of capture in a bi-ventricular pacing system.

In view of Applicant's belief that neither Brownlee et al in view of Lu nor Lu in view of Brownlee et al renders the subject matter of independent claim 1 as being obvious, modifying either of those combinations in view of the further teachings of Van Dam et al and/or Bradley would not result in a structure comparable to the

subject matter of claims 7-8 from the subject matter of claim 14, which depend from claim 1.

All claims of the application are therefore submitted to be in condition for allowance, and early reconsideration of the application is respectfully requested.

Submitted by,

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I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on August 1, 2006.

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